CEO of Brown & Williamson, conceded under questioning that Brown & Williamson uses high-nicotine blends in low-tar products, but asserted that "*[w]hat we were trying to do was maintain a certain amount of nicotine which gives us better taste.*"[712]

Based on the evidence in the record, the Agency finds the manufacturers' contention that they do not control and manipulate nicotine levels in blends not to be credible. The high nicotine content in the blends of low-tar cigarettes is not an accident. It necessarily reflects the deliberate design choices of the manufacturers. Moreover, the manufacturers' argument that they do not control and manipulate the nicotine content of blends is in fundamental conflict with their assertions that they manipulate nicotine for taste.

For several reasons, the Agency also does not regard the manufacturers' assertion that they control and manipulate nicotine only for taste to be credible. First, the manufacturers' assertion is contradicted by numerous internal statements of senior researchers and officials in the tobacco industry, made public during the Agency's investigation. As discussed above in section II.C.2., many senior researchers and officials within the industry explicitly acknowledge that nicotine provides desired pharmacological effects to consumers, and refer to cigarettes as a "dispenser for a dose unit of nicotine,"[713] a "nicotine delivery device,"[714] "a vehicle for delivery of nicotine,"[715] "the means of

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[712] *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Congress, 2d Sess. 227 (Jun. 23, 1994) (statement of Thomas Sandefur) (emphasis added). *See* AR (Vol. 709 Ref. 3).

[713] Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5. *See* AR (Vol. 12 Ref. 133).

[714] Philip Morris Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-named *Table*, at 5. *See* AR (Vol. 531 Ref. 122).

providing nicotine dose in a metered fashion,"[716] and a device that provides the smoker "very flexible control over titrating his desired dose of nicotine."[717] Other senior executives have stated that the cigarette industry is "in the business of selling nicotine, an addictive drug . . ."[718] and that "a good part of the tobacco industry is concerned with the administration of nicotine to consumers."[719] The industry's argument that high-nicotine blends are used in cigarettes only for taste cannot be reconciled with the industry's own internal statements that cigarettes are intended to deliver pharmacological doses of nicotine to consumers. Indeed, one Philip Morris document quoted by the company in its comments calls nicotine a "*tasteless*" constituent of tobacco.[720]

Second, the manufacturers' position on nicotine and taste cannot be reconciled with the industry's record of extensive research into nicotine pharmacology. In contrast, very little of the industry's research has examined the role of nicotine in taste. In their comments the cigarette manufacturers cite only a handful of industry studies on this subject. FDA has reviewed all of these studies and finds that they do not substantiate the industry's claim that nicotine's effects on taste are the reason consumers smoke. *See*

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[715] Teague, CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1. *See* AR (Vol. 531 Ref. 125).

[716] Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference, Session I, slides (Jul. 9-12, 1984), at BW-W2-03242. *See* AR (Vol. 24 Ref. 315).

[717] *Transdermal Nicotine Patches,* at 2. *See* AR (Vol. 531 Ref. 124).

[718] Yeaman A (Brown & Williamson), *Implications of Battelle Hippo I and II and the Griffith Filter* (Jul. 17, 1963), at 4. *See* AR (Vol. 21 Ref. 221).

[719] Green SJ (BATCO), *BAT Group Research* (Sep. 4, 1968), at 2. *See* AR (Vol. 15 Ref. 192).

[720] Philip Morris Inc., Comment (Apr. 19, 1996), at 64-65 (emphasis added), citing, "Merit Team Second Speaker" (Jan. 14, 1976). *See* AR (Vol. 700 Ref. 226).

section II.B.2.c., above. Philip Morris's comments do state that Philip Morris conducted sophisticated investigations into flavor using an EEG-assisted "olfactometer." Yet according to Philip Morris, "*[n]one of that 'olfactometer' work involved nicotine at all*"[721]—an omission that conflicts with the industry's assertion that nicotine has an important role in flavor.

By contrast, the industry has conducted or funded hundreds of studies on nicotine pharmacology, focused primarily on nicotine's effects on brain function. Manufacturers have learned through this research that nicotine has the hallmark characteristics of an addictive drug, *see* section II.C.3., above, and "abuse liability";[722] that nicotine changes patterns of human brain waves in a manner associated with anxiety relief; [723] and that "[n]icotine is an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical and physiological responses."[724]

The research conducted by several companies to find "nicotine analogues" to replace nicotine in cigarettes provides an especially clear illustration that the industry regarded nicotine's primary effects as pharmacological, not flavor-related. The goal of this research was to develop a molecule that would "mimic nicotine's effect in the

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[721] *Id.* at 47 (emphasis added).

[722] *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives,* 103d Cong., 2d Sess. 33 (Apr. 28, 1994) (testimony of Victor DeNoble). *See* AR (Vol. 708 Ref. 2).

[723] Pritchard WS (R.J. Reynolds Tobacco Co.), Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490. *See* AR (Vol. 3 Ref. 23-2).

[724] BATCO, *Method for Nicotine and Cotinine in Blood and Urine* (May 21, 1980), at 2. *See* AR (Vol. 23 Ref. 300-1).

brain"[725] and "possess[] the desired features of brain stimulation and stress-relief"[726] not to find substitute compounds with the same flavor characteristics as nicotine.

Third, the manufacturers' contention that they blend for taste and not for pharmacological effects conflicts with their assertions that they blend and design their products to meet consumer preferences. As discussed above in sections II.A. and II.B., the primary reason consumers smoke is to satisfy their addiction and obtain the other pharmacological effects of nicotine, such as sedation and stimulation. This fact is widely accepted by both the scientific community and researchers and officials within the tobacco industry. Cigarette manufacturers that strive to satisfy smokers' demands must necessarily design and blend cigarettes that produce pharmacological effects, including satisfying the needs of addicted smokers. This issue is further discussed in section II.C.4.f., below.

The Agency does not find that flavor is irrelevant in the blending process. To the contrary, the Agency agrees that one of the objectives in tobacco blending is to provide flavorful cigarette smoke. In the competitive cigarette marketplace, a cigarette that satisfied consumers' pharmacological demands for nicotine but did not taste good would be unlikely to be a commercial success. RJR's experience with Premier may, in fact, confirm this point.

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[725] *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 33 (Apr. 28, 1994) (testimony of Victor DeNoble). *See* AR (Vol. 708 Ref. 2).

[726] Minutes of BATCO Research Conference at Hilton Head, SC (Sep. 24-30, 1968), at 3. *See* AR (Vol. 14 Ref. 172-2).

II.C.4.

The Agency finds, however, that a cigarette that tasted good but did not satisfy consumers' pharmacological demands for nicotine would be even more unlikely to be a commercial success. As Ian Uydess, the former Philip Morris scientist, states:

> [A] cigarette having satisfactory ('high enough') nicotine levels but marginal flavor, stood a better chance of being 'accepted' in the market place than a somewhat better tasting product with zero or ultra-low levels of nicotine ('not enough').
>
> . . . *Tobacco companies like Philip Morris learned a long time ago that it was hard to get people to stay with a good tasting product if the nicotine level was too low.*[727]

In other words, to produce a cigarette that smokers will find acceptable, the cigarette manufacturer must use tobacco blends that provide consumers the desired pharmacological effects of nicotine.

For these reasons, FDA concludes that cigarette manufacturers use nicotine-rich blends in low-tar cigarettes to ensure that these cigarettes deliver pharmacologically active doses of nicotine.

b. The Manufacturers Use Filtration and Ventilation Technologies That Selectively Remove More Tar than Nicotine and That Allow Smokers To Inhale More Nicotine than the Measured Levels

The evidence before the Agency also supports a finding that cigarette manufacturers use cigarette filters and ventilation to manipulate nicotine deliveries. Especially in low-tar products, the available evidence indicates that cigarette manufacturers and their filter suppliers have engineered filtration and ventilation systems to bring about greater reductions in tar than in nicotine, thereby increasing the nicotine/tar ratio. According to William Farone of Philip Morris, "modification of the construction of

[727] Declaration of Uydess IL (Feb. 29, 1996), at 11, 13 (emphasis added). *See* AR (Vol. 638 Ref. 1).

the cigarette such as filter type, the type of filter material used, the number and placement of ventilation holes, [and] the density, composition and porosity of the cigarette paper" is the second principal means of controlling nicotine used by the industry.[728]

The effect of filtration and ventilation on nicotine deliveries is recognized in the technical tobacco literature. According to an article by a researcher at Lorillard Tobacco Co.:

> [V]entilated filters caused a significant drop in the amount of nicotine retained on the filter.
> . . . *[S]moke from ventilated cigarettes is relatively enriched in nicotine.*[729]

Similarly, scientists at Eastman Kodak Co., a manufacturer of cigarette filters, have observed that "*[a]s ventilation is increased, the nicotine content . . . increases markedly.*"[730]

Indeed, some filter manufacturers have openly promoted the ability of their filters to increase nicotine/tar ratios. For instance, Filtrona Ltd.'s Filtrona Ratio filter was promoted as "a new option available to cigarette designers which allows management of the yield ratios of important smoke components relative to tar, [including] . . . nicotine."[731]

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[728] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 5. *See* AR (Vol. 638 Ref. 2).

[729] Norman V, Ihrig AM, Shoffner RA (Lorillard Tobacco Co.), The effect of tip dilution on the filtration efficiency of upstream and downstream segments of cigarette filters, *Beitrage zur Tabakforschung International*, Jul. 1984;12(4):178-185, at 184 (emphasis added). *See* AR (Vol. 103 Ref. 923).

[730] Kiefer JE (Eastman Kodak Co.), Ventilated filters and their effect on smoke composition, *Recent Advances in Tobacco Science* (1979), at 78. *See* AR (Vol. 28 Ref. 465).

[731] Papers, filters, and tipping, *Tobacco Reporter*, Apr. 1985;112(4):32. *See* AR (Vol. 351 Ref. 5624).

When applied to commercial brands, this filter increased nicotine deliveries by over 25%, while leaving tar deliveries virtually unchanged.[732]

In their comments on the Jurisdictional Analysis, the cigarette manufacturers acknowledge that filtration and ventilation in low-tar cigarettes produce enhanced nicotine/tar ratios, but they argue that this is strictly an unavoidable physical phenomenon—not a design feature. The administrative record does not support their position.

Contrary to the cigarette manufacturers' contention, the filter manufacturers describe the role of filters and ventilation as not simply removing tar and nicotine according to immutable proportions determined by the laws of physics. Filters are highly engineered products that are "*designed exclusively to yield the maximum satisfaction from a carefully chosen tobacco blend.*"[733] The object of filters and ventilation is to "control the yield of the many constituents that the smoker receives" and to "*act[] more as a smoke modifier* than as an absolute filter which removes all particles of a known size."[734]

As described above in section II.C.3.e., the administrative record indicates that filter manufacturers have developed numerous strategies for independently changing tar and nicotine deliveries. When the cigarette manufacturer selects a filter and ventilation design, therefore, the cigarette manufacturer's choices necessarily affect the relative

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[732] *Id.*

[733] Philips JA (Filtrona International Ltd.), Filters for cigarettes: an integral part of the cigarette, *Tobacco Reporter* (Oct. 1981), at 34 (emphasis added). *See* AR (Vol. 351 Ref. 5624).

[734] *Id.* at 34 (emphasis added).

nicotine and tar deliveries. A decision to place the ventilation holes close to the tobacco rod will increase relative nicotine deliveries,[735] as will a decision to increase the porosity of the cigarette paper.[736] The use of increasingly porous perforated cigarette paper will "*selectively increase nicotine.*"[737] A decision to rely on relatively more ventilation and relatively less filtration is another "tool[]" that "increas[es] nicotine delivery without changing tar delivery."[738] Likewise, when manufacturers decide to increase the pH of the filter through use of an additive, this increases cigarette nicotine delivery "independently" of tar delivery.[739] Thus, contrary to the position of the cigarette manufacturers, there are many technical choices that manufacturers make in filtration and ventilation design that determine the extent to which the cigarette filter and ventilation will increase nicotine deliveries relative to tar deliveries.

The statement of William Farone corroborates the evidence showing that deliberate design decisions have caused the selective filtration and ventilation observed in

[735] Kiefer JE (Eastman Kodak Co.), Ventilated filters and their effect on smoke composition, *Recent Advances in Tobacco Science* (1979), at 79. *See* AR (Vol. 28 Ref. 465).

[736] McMurtrie A, Litringer EF, Wu DT (Brown & Williamson), *Cigarette Paper Effects on Tar/Nicotine and CO/Tar Ratios,* 35th Tobacco Chemists' Research Conference, Winston-Salem, North Carolina (Oct. 6-9, 1981). *See* AR (Vol. 639 Ref. 2).

[737] Owens WF Jr. (Ecusta Paper and Film Group), *Effect of Cigarette Paper on Smoke Yield Composition,* 32d Tobacco Chemists' Research Conference, Montreal, Canada (1978) (emphasis added). *See* AR (Vol. 639 Ref. 10).

[738] Selke WA, Making the cigarette do just what you want it to do, *Journal Tobacco International* 1983:12. *See* AR (Vol. 102 Ref. 896).

[739] Lee BM (Eastman Kodak Co.), *Modification of Nicotine to Tar Ratio in Cigarette Smoke,* 42d Tobacco Chemists' Research Conference, Lexington, Kentucky (Oct. 2-5, 1988), at 33. *See* AR (Vol. 639 Ref. 2).

low-tar cigarettes. According to Farone, "[t]he cigarette industry . . . *altered the cigarette filter in order to increase nicotine delivery.*"[740] Specifically, he states:

> *Filter design and ventilation allowed the design and manufacture of cigarettes that removed a higher percentage of tar than nicotine.* Selective filtration was accomplished by altering the technical specifications for a filter, e.g. by selecting different filter tow combinations, varying the denier per filament, and deciding whether or not to use additives in the filter. . . . *[A]ppropriate filters were identified to attain a predetermined nicotine/tar ratio.*[741]

The example of the regular-length Benson & Hedges filtered cigarettes that Congressman Henry A. Waxman described on the floor of the U.S. House of Representatives in July 1995 also contradicts the position of the cigarette industry.[742] The cigarette industry maintains that high nicotine/tar ratios are unavoidable in ultra-low-tar cigarettes because the high levels of filtration and ventilation in these cigarettes inevitably remove more tar than nicotine. The Benson & Hedges example, however, shows that (1) ultra-low-tar and nicotine levels can be achieved without increasing the ratio of nicotine to tar and (2) the high nicotine/tar ratios typically observed in cigarettes with ultra-low tar levels are therefore the result of deliberate design choices of manufacturers.

The Benson & Hedges cigarette was marketed as an ultra-low-tar cigarette from 1978 to 1985, with tar levels consistently below or near 1 milligram.[743] In three of those

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[740] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 11 (emphasis added). *See* AR (Vol. 638 Ref. 2).

[741] *Id.* (emphasis added).

[742] Remarks of Waxman HA, 141 Cong. Rec. H8009-8010 (daily ed. Jul. 31, 1995). *See* AR (Vol. 27 Ref. 376a).

[743] *Id.*

years (1978, 1984, and 1985), the nicotine levels were also proportionately low, producing a normal nicotine/tar ratio.[744] Thus, in these years, the filtration and ventilation technologies used by the manufacturer to reduce tar deliveries did not selectively increase nicotine deliveries. In contrast, from 1979 to 1983, the nicotine levels were elevated relative to the tar levels, producing a high nicotine/tar ratio.[745] These changes in the nicotine/tar ratio were not due to chance.[746] These facts thus establish that the manufacturer, in this case Philip Morris, had the technical ability to achieve ultra-low-tar levels without causing nicotine levels to be relatively enhanced.

The evidence also indicates that cigarette manufacturers also use "elasticity" technologies, principally ventilation techniques that can be readily blocked, to allow smokers to increase their nicotine intakes above the levels measured on smoking machines. One example is Brown & Williamson's Barclay cigarette. This cigarette was first introduced as an ultra-low-tar cigarette in 1981. As noted above in section II.C.4.a.ii., tests in 1982 showed that the tobacco in the Barclay blend had a higher nicotine concentration than any other cigarette brand tested. Barclay also had more total nicotine in the tobacco rod than any other cigarette tested. For instance, Barclay had *over 60% more total nicotine* in the cigarette rod (12.80 mg per cigarette) than regular-strength Lucky Strike (7.92 mg per cigarette). Yet despite its high nicotine levels, Barclay had the second lowest nicotine yields of any cigarette tested, as measured by the FTC smoking machine method. Thus, even though, as noted, Barclay had over 60% more nicotine in

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[744] *Id.*

[745] *Id.*

[746] *Id.*